

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

JOHNS HOPKINS UNIVERSITY,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 13-1853-LPS
	:	
454 LIFE SCIENCES CORPORATION,	:	
	:	
Defendant.	:	

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MEMORANDUM OPINION

May 2, 2016
Wilmington, Delaware



STARK, U.S. District Judge:

Pending before the Court are partial motions for summary judgment filed by Johns Hopkins University (“JHU” or “Plaintiff”) and 454 Life Sciences Corporation (“454” or “Defendant”). JHU filed this action pursuant to 35 U.S.C. § 146 on November 6, 2013 to review the Decision and Final Judgment of the Board of Patent Appeals and Interferences (“the Board”) in Interference No. 105,857 (“the Interference”). (*See* D.I. 1 at 1, 8) JHU is the junior party in the Interference and 454 is the senior party. (*See id.*) The interfering applications are U.S. Patent Application Nos. 12/361,690 (D.I. 39 Ex. 1) (JHU’s “’690 application”) and 13/33,240 (D.I. 39 Ex. 5) (454’s “’240 application”). The Interference involves a single count (“Count”)¹ with the interfering subject matter represented by claim 1 of JHU’s ’690 application and claim 52 of Defendant’s ’240 application. (*See* D.I. 44 at 1; D.I. 45 at 1)

Claim 1 of the ’690 application is representative and recites the following:

A method for analyzing nucleic acid sequences comprising:

- (a) generating a plurality of molecules of a fragment of deoxyribonucleic acid;
- (b) delivering the plurality of molecules of the fragment of deoxyribonucleic acid into aqueous microreactors in a water-in-oil emulsion such that a plurality of aqueous microreactors comprise a single molecule of the fragment of deoxyribonucleic acid, a single bead capable of hybridizing the fragment of deoxyribonucleic acid, and reagents necessary to perform deoxyribonucleic acid amplification;

¹In an interference, “[t]he applicant must identify at least one patentable claim from every application or patent that interferes for each count. A count is just a description of the interfering subject matter, which the Board of Patent Appeals and Interferences uses to determine what evidence may be used to prove priority under 35 U.S.C. § 102(g)(1).” Manual of Patent Examining Procedure (“MPEP”) § 2304.02(b).

- (c) amplifying the fragment of deoxyribonucleic acid in the microreactors to form amplified copies of said fragment of deoxyribonucleic acid bound to beads in the microreactors;
- (d) determining presence of amplified copies of said fragment of deoxyribonucleic acid bound to a bead.

(D.I. 44 at 2-3)

The Court held a claim construction hearing on June 9, 2015 and issued a memorandum opinion on claim construction. (D.I. 56) Thereafter, the parties filed summary judgment motions, completing briefing on them on February 16, 2016. (*See* D.I. 69, 71, 76, 78, 81, 83) JHU moves for partial summary judgment that JHU's priority date with respect to the Count is no later than June 5, 2003 and that three of 454's U.S. Patent Applications – Nos. 60/456,592 ("592 application"), 60/465,071 ("071 application"), and 13/033,240 ("240 application") – fail to provide adequate written description or enablement for the Count, as required by 35 U.S.C. § 112. (D.I. 68) ("JHU's Motion") 454 moves for partial summary judgment that 454's priority date with respect to the Count is April 23, 2003, the filing date of 454's '071 application. (D.I. 70) ("454's Motion") The Court held a hearing on the parties' summary judgment motions on March 1, 2016. (*See* Transcript (D.I. 90) ("Tr."))

For the reasons discussed below, the Court will grant in part and deny in part JHU's Motion and deny 454's Motion.

I. LEGAL STANDARDS

A. Summary Judgment

Pursuant to Rule 56(a) of the Federal Rules of Civil Procedure, "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact

and the movant is entitled to judgment as a matter of law.” The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). An assertion that a fact cannot be – or, alternatively, is – genuinely disputed must be supported either by citing to “particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials,” or by “showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then “come forward with specific facts showing that there is a genuine issue for trial.” *Matsushita*, 475 U.S. at 587 (internal quotation marks omitted). The Court will “draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the nonmoving party must “do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita*, 475 U.S. at 586; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment “must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue”) (internal quotation marks omitted). The “mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;” a factual dispute is genuine only where “the evidence is such that a reasonable jury could return a verdict for the nonmoving

party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial”). Thus, the “mere existence of a scintilla of evidence” in support of the nonmoving party’s position is insufficient to defeat a motion for summary judgment; there must be “evidence on which the jury could reasonably find” for the nonmoving party. *Anderson*, 477 U.S. at 252.

B. Patent Validity Under 35 U.S.C. § 112

Paragraph 1 of 35 U.S.C. § 112 states in pertinent part:

The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same^[2]

The statute sets out separate requirements for written description and enablement. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (holding that written description and enablement requirements are separate). These requirements “often rise and fall together.” *Id.* at 1352. The parties agree that, in a case brought under § 146 arising from an interference, invalidity under § 112 must be proved by a preponderance of the evidence. (See Tr.

^[2]The patent statute was amended in September 2011 by the America Invents Act (“AIA”). Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 300-01 (2011). The pre-AIA version of § 112 applies in this case. The post-AIA version of this portion of the statute (§ 112(a)) is identical to the pre-AIA verison.

at 31-32, 45) The Court agrees that a preponderance of the evidence standard applies. *See Bruning v. Hirose*, 1998 WL 690851, at *3-5 (Fed. Cir. Sept. 29, 1998).

1. Written Description

Whether a specification satisfies the written description requirement is a question of fact. *See GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725, 729 (Fed. Cir. 2014); *see also Alcon, Inc. v. Teva Pharms. USA, Inc.*, 664 F. Supp. 2d 443, 468 (D. Del. 2009) (“Satisfaction of the written description requirement is a fact-based inquiry, depending on ‘the nature of the claimed invention and the knowledge of one skilled in the art at the time an invention is made and a patent application is filed.’”) (quoting *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008)). Despite being a question of fact, the issue of invalidity for lack of written description is amenable to summary judgment. *See, e.g., Carnegie Mellon*, 541 F.3d at 1126-28 (affirming summary judgment of invalidity for lack of written description); *see also Helicos Biosciences Corp. v. Illumina, Inc.*, 888 F. Supp. 2d 519, 530-31 (D. Del. 2012) (“While compliance with the written description requirement is a question of fact, the issue is ‘amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party.’”) (quoting *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008)).

To comply with the written description requirement, a patent’s specification “must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed.” *Ariad*, 598 F.3d at 1351 (internal brackets and quotation marks omitted). “[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing

date.” *Id.* “[T]he hallmark of written description is disclosure. Thus, ‘possession as shown in the disclosure’ is a more complete formulation” of the written description requirement. *Id.* “[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” *Id.* “[T]he written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement.” *Id.* at 1352. However, “a description that merely renders the invention obvious does not satisfy the requirement.” *Id.*

2. Enablement

“Enablement is a question of law based on underlying factual findings.” *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012). “‘To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.’” *Id.* (quoting *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997)) (internal quotation marks omitted). “Enablement serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention.” *Id.* at 1380-81. “Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage.” *Id.* at 1381. “The scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.” *Id.* (internal quotation marks omitted).

“Whether undue experimentation is needed is not a single, simple factual determination,

but rather is a conclusion reached by weighing many factual considerations.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors include “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *Id.* Although “a specification need not disclose what is well known in the art,” “[t]ossing out the mere germ of an idea does not constitute enabling disclosure.” *Genentech*, 108 F.3d at 1366. A patent “cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification.” *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 941 (Fed. Cir. 2010).

C. Broader Reasonable Interpretation

The various terms of representative claim 1 of the ’690 application are given their broadest reasonable interpretation in light of the “originating disclosure” for purposes of analyzing written description and enablement of the Count. *See ULF Bamberg v. Dalvey*, 2016 WL 890682, at *2 (Fed. Cir. Mar. 9, 2016). The Court previously determined that the “originating disclosure” for the Count is JHU’s ’690 application and its prosecution history. (See D.I. 56 at 8) (“[T]he ’690 application and its prosecution history are the proper sources of intrinsic evidence for interpreting the disputed claim language. To the extent that the ’690 application’s prosecution history includes 454’s patent(s) or application(s), however, these would also qualify as relevant intrinsic evidence. The Court rejects 454’s proposal to rely on the ’240 application and related/incorporated applications to the exclusion of the ’690 application.”)

D. Priority of Invention

The junior party in an interference (JHU in this case) “must show priority by a preponderance of the evidence.” *Brown v. Barbacid*, 276 F.3d 1327, 1332 (Fed. Cir. 2002). “Priority of invention and its constituent issues of conception and reduction to practice are questions of law predicated on subsidiary factual findings.” *Singh v. Brake*, 317 F.3d 1334, 1340 (Fed. Cir. 2003). In an interference, “all that is necessary for a party to be entitled to benefit of an earlier filed application for priority purposes is compliance with 35 U.S.C. § 112 with respect to at least one embodiment within the scope of the count.” *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1362 (Fed. Cir. 2006) (internal brackets and quotation marks omitted). In *Hunt v. Treppschuh*, 523 F.2d 1386, 1389 (C.C.P.A. 1975), the Court of Customs and Patent Appeals distinguished between requirements under § 112 for applications serving as bases for priority, on the one hand, and interfering applications which have the potential to ripen into issued patents, on the other:

Hunt’s parent application is relied upon as a prior constructive reduction to practice; whereas in [*Smith v. Horne*, 450 F.2d 1401 (C.C.P.A. 1971)], the disclosure was relied upon for a right to make the count. In the latter situation the requirements of the first paragraph of 35 U.S.C. § 112 must be satisfied for the full scope of the count. In the former, however, the § 112, first paragraph requirements need only be met for an embodiment within the count.

As applied to this case, the holdings in *Falko* and *Hunt* require 454’s ’592 and ’071 applications – which 454 relies on as bases for priority – to describe and enable at least one embodiment within the scope of the Count. 454’s ’240 application, by contrast, must describe and enable the *full scope* of the Count.

“Priority of invention ‘goes to the first party to reduce an invention to practice unless the other party can show that it was the first to [1] conceive the invention and [2] that it exercised reasonable diligence in later reducing that invention to practice.’” *Barbacid*, 276 F.3d at 1337 (quoting *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993)). “Conception is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice.” *In re Steed*, 802 F.3d 1311, 1320 (Fed. Cir. 2015) (internal quotation marks omitted). To show conception, “a party must show possession of every feature recited in the count, and that every limitation of the count must have been known to the inventor at the time of the alleged conception.” *Coleman v. Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985). The inventor “must provide independent corroborating evidence in addition to his own statements and documents.” *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1375 (Fed. Cir. 2009) (internal citation omitted). Corroboration is subject to a “rule of reason” analysis. *Reese v. Hurst*, 661 F.2d 1222 (C.C.P.A. 1981). “Accordingly, a tribunal must make a reasonable analysis of all of the pertinent evidence to determine whether the inventor’s testimony is credible.” *Kridl v. McCormick*, 105 F.3d 1446, 1450 (Fed. Cir. 1997).

As to the second requirement for proving priority of invention, reduction to practice requires continuous diligence throughout the entire “critical period” between conception and reduction to practice. *See Monsanto Co. v. Mycogen Plant Sci., Inc.*, 261 F.3d 1356, 1369 (Fed. Cir. 2001); *see also* MPEP § 715.07(a) (“Under 37 CFR 1.131(a), the critical period in which diligence must be shown begins just prior to the effective date of the reference or activity and ends with the date of a reduction to practice, either actual or constructive . . .”). As the Court of

Appeals for the Federal Circuit has explained,

there need not necessarily be evidence of activity on every single day if a satisfactory explanation is evidenced. . . . Proof of reasonable diligence, however, does not require a party to work constantly on the invention or to drop all other work. . . . Additionally, determining whether the required “reasonable diligence” has been satisfied is a case specific inquiry.

Monsanto, 261 F.3d at 1369 (internal quotation marks and citations omitted).

II. LEVEL OF ORDINARY SKILL IN THE ART

The Court asked the parties to address the level of skill for a person having ordinary skill in the art (“POSA”). (See D.I. 84) The parties submitted a joint letter articulating their disputes regarding the POSA. (See D.I. 85) The parties’ primary dispute focuses on whether a POSA would have been familiar with emulsion-based PCR. JHU argues that a POSA “would have been familiar with regular PCR **but not** emulsion-based PCR as it was not commonly practiced then.” (D.I. 46-1 Ex. 4 at 5) 454 argues that a POSA **would** have been familiar with emulsion-based PCR. (D.I. 50-4 at 4) This is a genuine dispute of fact, although whether it is material to resolution of the pending motions is unclear. In an abundance of caution, the Court will apply the level of ordinary skill in the art articulated by the nonmoving party in deciding each of the summary judgment motions. *See Reeves*, 530 U.S. at 150 (2000) (“[T]he court must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.”).

III. JHU’S PARTIAL MOTION FOR SUMMARY JUDGMENT (D.I. 68)

JHU moves for partial summary judgment that its priority date with respect to the Count is no later than June 5, 2003 and that 454’s ’592, ’071, and ’240 applications fail to provide

adequate written description or enablement for the Count. The Court addresses each of these issues below.

A. JHU's Priority Date

JHU moves for partial summary judgment that its priority date for the Count is no later than June 5, 2003. The record before the Board was duly admitted by the Court and is part of the record in this case. (*See generally* D.I. 21-32, D.I. 35) The Court is tasked with making *de novo* factual findings with respect to evidence not presented to the Board. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1347 (Fed. Cir. 2000). Moreover, if and when the Court hears live testimony that may be the same or similar as testimony submitted to the Board in the form of affidavits or deposition transcripts, the Court will make *de novo* factual findings. *See id.* Documentary evidence that was submitted to the Board is treated “as if [it were] originally taken and produced” in the District Court. *See id.* Ultimately, the Court is tasked with conducting a *de novo* determination of the issue of priority.³ *See Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 659 F.3d 1186, 1191 (Fed. Cir. 2011) (“In accordance with statute and precedent, the district court appropriately considered additional evidence and conducted a *de novo* determination of the issue of priority under § 146.”).

JHU cites the Board’s decision in JHU’s favor on this issue as support for its motion. (*See* D.I. 23-6 Document 370 at 4-7) The Board determined that JHU had established “by a preponderance of the evidence that it conceived of the subject matter of [the Count] by June 5, 2003” and that the JHU inventors “were reasonably diligent for the month June 5, 2003 until the

³The Federal Circuit has characterized § 146 actions as hybrid appeals and trials *de novo*. *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1296 (Fed. Cir. 2014).

filings of provisional application No. 60/485,301 on July 5, 2003, i.e., JHU's constructive reduction to practice." (*Id.* at 7)

With respect to conception, the Board found that a manuscript ("June 5, 2003 Manuscript") (D.I. 24-13 JHU Ex. 2042) sent by Bert Vogelstein – one of the inventors of the '690 application – to Dr. Scott Kern – a non-inventor – disclosed a conception of the Count. (*See* D.I. 23-6 Document 370 at 4-7) As corroboration of the June 5, 2003 conception date, the Board credited Dr. Kern's testimony that he reviewed and provided comments on the manuscript "on or prior to June 5, 2003." (*Id.* at 5-7; Kern Decl., D.I. 24-6 JHU Ex. 2023 at 2-3) The Board found that the June 5, 2003 Manuscript was submitted for publication on June 6, 2003 to the journal *Proceedings of the National Academy of Sciences* ("PNAS"), which published an article disclosing the substance of the manuscript on July 22, 2003. (*See* D.I. 23-6 Document 370 at 5)

The Board further found that the June 5, 2003 Manuscript disclosed the subject matter of the Count. For example, the Board cited "Figure 1 and its figure legend" in the June 5, 2003 Manuscript as disclosing step (b) of the Count by depicting and describing "aqueous compartments (white circles in the gray oil later) [that] contain an average of <1 template molecule and <1 bead," including "a plurality [of] (two) microreactors, where each contains one template DNA and one bead only." (*Id.* at 5-6) In addition, the Board determined that the June 5, 2003 Manuscript "refer[s] to using 'PCR products' as templates in the described method, which are generated as stated in [step] (a) of [the Count]." (*Id.* at 6)

With respect to diligence until reduction to practice, the Board credited JHU's "Diligence Chart" as proving, by a preponderance of the evidence, that the "JHU inventors were reasonably diligent for the month from June 5, 2003 until the filing of provisional application No.

60/485,301” (“‘301 provisional application”) on July 5, 2003, “i.e., JHU’s constructive reduction to practice.” (*Id.* at 7) (citing Diligence Chart (D.I. 24-3 Document 241) at 56-59 (listing evidence, on day-by-day basis between June 5 and July 5, 2003, of actions performed to reduce to practice subject matter of Count))

In addition to relying on the Board’s findings, JHU relies on an expert report by Dr. Sanjay Tyagi. Dr. Tyagi states that he “reviewed documents previously submitted by [JHU] to demonstrate conception prior to June 6, 2003” and that his review “indicated that the content of the manuscript of June 5, 2003 was identical in virtually every respect to the article [PNAS] published on July 22, 2003.” (D.I. 74-2 Ex. 3 at 1-2) Moreover, Dr. Tyagi states in his report that there are “no substantive differences” between the substantive content of the June 5, 2003 Manuscript, the PNAS article, and the ‘301 provisional application relied on by JHU as a constructive reduction to practice. (*See id.* at 28) Based on his review, Dr. Tyagi concludes that the JHU inventors “had a complete conception of the subject matter of the Count at least by June 5, 2003.” (*Id.*)

454 attempts to rely on the same arguments 454 presented to the Board in opposition to JHU’s priority motion. (*See* D.I. 78 at 35-36; *see also* Tr. at 34 (“[O]ur attack [on JHU’s claimed priority date] is the one that we made back in the Patent Office [“PTO”]. So we renewed that same attack.”)) 454 argues that it “is entitled to rely on the **arguments** of record [before the Board] as if presented in the district court.” (D.I. 78 at 36) (emphasis added) It is true that 454 can revive arguments it made before the Board (and it can of course rely on the record presented to the Board), but it cannot do so in a manner that fails to provide this Court the input it needs in order to make an informed decision. Nor can a litigant rely on “incorporation by reference” in

order to evade the Court's page limits. *See Masimo Corp. v. Philips Elec. N. Am. Corp.*, 62 F. Supp. 3d 368, 376 (D. Del. 2014) ("Underlying briefs cannot be 'incorporated by reference' as a way of avoiding the page limits."). Here, 454's efforts to incorporate by reference its arguments before the Board threaten to eviscerate the page limits set in the Scheduling Order. (See D.I. 10 ¶ 17(b)) (setting page limits for dispositive motions) The Court could grant JHU's motion with respect to the June 5, 2003 priority date based solely on 454's failure to include its opposition arguments in its brief.

But the Court will also address the merits of 454's position. Having considered the arguments 454 presented to the Board (*see* D.I. 23-5 Document 257 at 1-15) as if they were presented in this case, the Court will grant JHU's priority motion, for the reasons articulated in the Board's decision (*see* D.I. 23-6 Document 370 at 4-7). Under *de novo* review, the Court further concludes that 454 fails to raise a genuine issue of material fact. 454 argued before the Board that Dr. Kern did not testify "as to what version of the manuscript" he reviewed. (D.I. 23-5 Document 257 at 2) Even if this were true, however, Dr. Kern's comments on the version of the manuscript that he reviewed – which Dr. Kern says he received from Vogelstein – indicate that the version Dr. Kern reviewed disclosed a conception of the Count. (*See* Kern Decl., D.I. 24-6 JHU Ex. 2023 at 4-5 (discussing water-and-oil emulsion; use of PCR products, genomic DNA, or cNDA as "templates;" single-bead "compartments;" and "microemulsions"); *see also* D.I. 23-6 Document 370 at 6-7 (Board decision discussing Dr. Kern's comments as corroborating JHU's conception date)) 454 does not attack the veracity of Dr. Kern's comments or the statements in his declaration with respect to the manuscript he received from Vogelstein. Therefore, 454 fails to raise a genuine issue of material fact with respect to the version Dr. Kern

reviewed.

454 argued before the Board that “further revisions” were made to the manuscript submitted to PNAS on June 6, 2003 before it was published. (*See* D.I. 23-5 Document 257 at 2) However, 454 does not point to any material differences between the June 5, 2003 Manuscript, the manuscript submitted to PNAS on June 6, 2003, or the PNAS article published in July 2003. Moreover, 454 fails to rebut JHU’s evidence showing that all elements of the Count are present in each of these documents. (*See, e.g.*, D.I. 23-6 Document 262 at 1-13) (explaining where each element of Count is found in June 5, 2003 Manuscript and describing Dr. Kern’s corroboration of June 5, 2003 Manuscript) Therefore, 454’s arguments regarding different versions of the Manuscript fail to raise a genuine issue of material fact.

Finally, 454 argued before the Board that JHU failed to demonstrate diligence in reduction to practice. (*See id.* at 3) 454 does not attack the veracity of the detailed Diligence Chart (D.I. 24-3 Document 241 at 56-59) provided by JHU to show reasonable diligence until reduction to practice. Instead, 454 again focuses on alleged deficiencies in Dr. Kern’s corroboration of the June 5, 2003 Manuscript. (*See* D.I. 23-5 Document 257 at 14-15) 454 points out that Dr. Kern’s “referee review form” containing comments on the June 5, 2003 Manuscript was unsigned and that there was no evidence to corroborate the version he reviewed. (*Id.* at 14) However, the relevant portions of Dr. Kern’s declaration remain unrebutted by any evidence or challenge from 454. Moreover, 454 has presented no evidence that Dr. Kern misrepresented his involvement with reviewing the June 5, 2003 Manuscript, or even why he would have a motivation to do so. 454’s arguments presented to the Board regarding JHU’s diligence in reduction to practice fail to raise a genuine issue of material fact.

JHU has met its burden at summary judgment by producing evidence which shows, by a preponderance of the evidence, conception and diligent reduction to practice sufficient to support a priority date of June 5, 2003. 454, on the other hand, has failed to raise any genuine issue of material fact with respect to the evidence relied on by JHU. Thus, the Court will grant JHU's motion for a June 5, 2003 priority date.

B. Whether 454's Applications Comply with 35 U.S.C. § 112

1. The '592 Application

a. Written Description

JHU moves for partial summary judgment that 454's '592 application lacks written description support for steps (a) and (b) of the Count. (*See* D.I. 69 at 9-17) Regarding step (a), JHU focuses on the "fragmenting methods" described in the '592 application, which are used to generate source DNA for step (a). (*See* D.I. 69 at 13) JHU argues that these methods "would not necessarily generate two or more copies of the same DNA fragment [as] required in step (a) of the Count." (*See id.*) 454's expert, Dr. Levy, counters JHU's arguments in his declaration in support of 454's opposition brief, opining: "The '592 [application] clearly describes multiple embodiments that will result in the generation of multiple copies of a single DNA fragment, and a person of ordinary skill in the art would have understood that from the explicit disclosures of the '592 provisional." (D.I. 80 at 7) (citing '592 application (D.I. 74-4) at 11-12) Dr. Levy continues: "[U]se of restriction enzymes will *always* result in the formation of identical fragments of DNA when a population of cells is digested." (*Id.*) (emphasis added) Dr. Levy's testimony creates a genuine issue of material fact with respect to whether the '592 application provides adequate written description for step (a).

Regarding step (b), JHU argues that the '592 application fails to "provide any description of delivery of [a] plurality of the molecules generated in step (a) into [an] aqueous microreactor. Moreover, the Court's claim construction requires that the molecules of the fragment of DNA be 'a nucleic acid molecule.'" (D.I. 69 at 14) (citing D.I. 56 at 15) Dr. Levy again counters JHU's arguments in his declaration, opining that the '592 application "clearly and unambiguously describes delivering the fragments generated according to step (a) into the microreactors in step (b)." (D.I. 80 at 13) Moreover, Dr. Levy states that "the previously generated sequence [from step (a)] is still intact [at step (b)], and so the same molecule of a fragment of deoxyribonucleotide is still present." (*Id.*) Dr. Levy's testimony creates a genuine issue of material fact with respect to whether the '592 application provides adequate written description for step (b).

b. Enablement

JHU moves for partial summary judgment that the '592 application fails to comply with the enablement requirement. (*See* D.I. 69 at 17-18, 19-20) JHU argues that the '592 application fails to enable step (a), arguing that the '592 application discloses "only passing references to many different sources of DNA and the methods of fragmentation without providing any guidance regarding ***the need or the conditions necessary*** to generate two or more molecules of a particular DNA fragment." (D.I. 69 at 17) (emphasis in original) Dr. Levy counters JHU's arguments by citing portions of the '592 application that disclose sequencing and sequence variation analysis, explaining that, in light of such disclosures, a POSA "would have understood the need to generate multiple copies of the same DNA fragment." (D.I. 80 at 14-15) Moreover, Dr. Levy states that the techniques disclosed in the '592 application "for generating a plurality of

molecules of a fragment of DNA" are "basic laboratory techniques," and that a POSA could have conducted, for example, "a restriction digest of genomic DNA (which was itself isolated using a commercially available method) without explicit direction as to the necessary 'conditions.'" (Id. at 15-16) Dr. Levy's statements create a genuine issue of material fact with respect to JHU's argument that the '592 application lacks an enabling disclosure for step (a).

JHU argues that the '592 application fails to enable the "full scope" of the Count. Specifically, JHU argues that the '592 application teaches delivery of only *single*-stranded DNA (and not *double*-stranded DNA) and that it teaches only *pre-hybridized* beads (and not beads that are *separated* from DNA fragments). (See D.I. 69 at 19-20) In an interference, "all that is necessary for a party to be entitled to benefit of an earlier filed application for priority purposes is compliance with 35 U.S.C. § 112 with respect to at least one embodiment within the scope of the count." *Falko*, 448 F.3d at 1362 (internal brackets and quotation marks omitted). Dr. Levy opines that the '592 application enables an embodiment within the scope of the Count. (See D.I. 80 at 18-19) Because the '592 application is only required to enable a single embodiment within the scope of the Count, Dr. Levy's testimony creates a genuine issue of material fact with respect to enablement of the Count by the '592 application.

The Court will deny JHU's motion with respect to JHU's claim that the '592 application fails to comply with the written description and enablement requirements.

2. The '071 Application

a. Written Description

JHU moves for partial summary judgment that 454's '071 application lacks written description support for steps (a) and (b) of the Count. (See D.I. 69 at 9-17) JHU's arguments

against the '071 application are similar to its arguments directed to the '592 patent, discussed above. (*See id.* at 12 ("The specification of the '592 Application suffers from the same flaw as the specification of the '071 Application and thus similarly fails to meet the written description requirement of 35 U.S.C. § 112 with respect to step (a) of the Count."); *id.* at 14 ("Neither the '071 nor '592 applications provide any description of delivery of the plurality of the molecules generated in step (a) into the aqueous microreactor."); *id.* at 15 ("Further, since the '071 and '592 applications only teach delivery of a fragment chemically bonded to a bead, they do not teach delivery of 'a nucleic acid molecule . . . ' as required by this Court's claim construction."))

JHU notes that the Board found that the '071 application lacked adequate written description of step (a) of the Count. (*See id.* at 9-11) (quoting relevant excerpts of Board decision) The Board found that "454 has not established (*e.g., by citing to data or expert testimony evidence*) that use of any such [restriction] enzymes would generate two or more molecules of a specific DNA fragment, or more specifically, that an ordinary artisan would understand that to be the case." (D.I. 23-4 Document 236 at 14) (emphasis added) In the instant proceedings, however, 454 *has* cited expert testimony of Dr. Levy in support of 454's argument that a POSA would have understood that the '071 application discloses possession of at least one embodiment of steps (a) and (b) of the Count. (*See* D.I. 78 at 15) ("As Dr. Levy has explained, a [POSA] would have known and understood that utilizing commercially available protocols for DNA isolation and restriction endonuclease digestion as taught by the '071 application will 'generate two or more copies of the same DNA fragment' as required by step (a).") (citing Levy Declarations) For the same reasons discussed above with respect to JHU's arguments against the '592 application's alleged lack of written description, Dr. Levy's testimony creates a genuine

issue of material fact with respect to the '071 patent. The Court cannot resolve this dispute at summary judgment.⁴

b. Enablement

JHU moves for partial summary judgment that 454's '071 application fails to enable steps (a) and (b) of the Count. (*See* D.I. 69 at 17-20) JHU presents identical arguments against the '071 and '592 applications with respect to alleged non-enablement of step (a) of the Count. (*See id.* at 17-18) For the same reasons discussed above with respect to the '592 application, Dr. Levy's testimony creates a genuine issue of material fact with respect to whether the '071 application enables step (a).

Regarding step (b), JHU argues that “[t]here is no recitation in the '071 application of how [the] aqueous microreactors [in step (b)] are created. There also is no teaching of delivering the molecule generated in step (a) to the microreactor according to step (b) anywhere in the '071 application.” (D.I. 69 at 18) Dr. Levy counters JHU's arguments, stating that any experimentation needed to practice step (b) would not be unreasonable or burdensome (i.e., “undue”), given the disclosure in the '071 application. (*See* D.I. 80 at 16-18) Dr. Levy's testimony creates a genuine issue of material fact on this issue.

JHU makes essentially the same argument regarding the '071 not enabling the “full scope” of the Count as discussed above for the '592 application. For the same reasons discussed above, the Court finds that there are genuine issues of material fact about whether the '071 application enables at least one embodiment that falls within the scope of the Count, which is all

⁴In making *de novo* factual findings with respect to the topics on which Dr. Levy has opined, the Court would benefit from hearing Dr. Levy's live testimony. *See generally Winner*, 202 F.3d at 1347.

that is required.

The Court will deny JHU's motion with respect to JHU's claim that the '071 application fails to comply with the written description and enablement requirements.

3. The '240 Application

JHU argues that 454's '240 application is invalid for failure to comply with the written description and enablement requirements. JHU's written description arguments were raised before the Board, but the Board exercised its discretion in declining to decide the issue. (See D.I. 22-1 Document 25 at 3-4) ("... Congress gave the Board discretion so that patentability would be reached when it aided resolution of the case rather than when it would frustrate resolution. In the present case, JHU's written description theory seems likelier to frustrate resolution than aid it.") The issue of enablement was *not* raised before the Board. (See D.I. 92 at 2) (454 arguing, without dispute from JHU, that "nowhere did JHU assert any attack on 454's enablement for its claims [before the Board].") As an initial matter, then, the Court must determine whether it is authorized to consider issues either not decided by or not raised before the Board.

As the parties did not express any concern about the Court reaching the merits of JHU's contentions with respect to the validity of 454's '240 application, the Court directed the parties to submit supplemental, post-hearing letter briefs on the issue. (See D.I. 89) In response, both parties point to the Federal Circuit's decision in *Troy v. Samson Mfg. Corp.*, 758 F.3d 1322, 1325 (Fed. Cir. 2014). JHU cites *Troy*, 758 F.3d at 1325-26, 1327-28, as well as *Kappos v. Hyatt*, 132 S. Ct. 1690, 1700-01 (2012) ("*Hyatt II*"), and argues "it is immaterial whether the issues of written description and enablement under Section 112 with respect to 454's '240 application were 'raised adequately' during the interference proceedings before the Board." (D.I. 91 at 2)

(quoting *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 (Fed. Cir. 1994), which JHU states was overruled by *Troy*, 758 F.3d at 1326) For its part, 454 states that *Troy* “would arguably allow JHU to present new arguments here that were not presented to the Board.” (D.I. 92 at 1)⁵

In *Troy*, the Federal Circuit held: “We conclude that to the extent that our prior precedent, *see, e.g.*, [*Conservolite*], held that new evidence on an issue not presented to the Board was generally to be excluded in district court proceedings, it is no longer viable following the Supreme Court’s [*Hyatt II*] decision.” *Id.* at 1326. Regarding *Hyatt II*, the *Troy* Court held: “We conclude that the Supreme Court’s decision in [*Hyatt II*] permits new evidence to be admitted [in § 146 proceedings] without regard to whether [an] issue was raised before the Board.” *Id.* at 1325. Hence, in *Troy*, the Federal Circuit interpreted the Supreme Court in *Hyatt II* as permitting introduction of “***new evidence on new issues***” in § 146 proceedings. *Troy*, 758 F.3d at 1325 (emphasis added). Accordingly, the Court will address JHU’s challenges to the ’240 application based on the written description and enablement requirements. *See generally* *Troy*, 758 F.3d at 1329 (remanding and instructing District Court to consider new evidence on new issue of inequitable conduct, which was raised for first time before District Court).

a. Written Description

JHU moves for partial summary judgment that the ’240 application fails to disclose step (a) of the Count and, therefore, that the ’240 application fails to comply with the written

⁵In response to the Court’s order for supplemental briefing, 454 argued that JHU did not timely raise challenges to the compliance of the ’240 application with § 112. (D.I. 92 at 1) The Court agrees with JHU that it timely raised these issues. (D.I. 93 at 1) Moreover, JHU timely moved for summary judgment and adequately briefed these issues. (*See generally* D.I. 68)

description requirement.⁶ (See D.I. 69 at 14) JHU’s arguments with respect to the ’240 application’s disclosure of step (a) are essentially the same as the arguments JHU makes with respect to the ’592 and ’071 applications. (See *id.*) As with the other applications, 454 offers expert testimony from Dr. Levy that creates a genuine issue of material fact with respect to this issue. (See D.I. 80 at 11) (“[M]y opinions with respect to the disclosures of the ’592 provisional in paragraphs 21-31 are equally applicable to the description in the ’240 application.”)

b. Enablement

JHU moves for partial summary judgment that the ’240 application fails to enable the full scope of the Count.⁷ Specifically, JHU argues: “The ’240 application merely adds a sentence beyond the disclosures of the ’071 and the ’592 applications that indicates that the beads can be delivered to the microreactors pre-hybridized or separate from the DNA fragments. This meager statement, however, is insufficient to enable the full scope of the claim.” (D.I. 69 at 20) (internal citation omitted) The Court previously construed the term “a single bead capable of hybridizing to the fragment” in step (b) to include within its scope pre-hybridized bead-fragment combinations. To the extent any doubt remains as to the meaning of this term, the Court further construes this term to include embodiments comprising a single bead *separate* from a fragment.

⁶JHU does not challenge, at summary judgment, the ’240 application’s compliance with the written description requirement for step (b).

⁷In connection with JHU’s enablement argument against the ’240 application, JHU argues that the ’240 application is anticipated by JHU’s PNAS article. (See D.I. 69 at 20) JHU’s argument is premised on the assumption that 454 cannot rely on its provisional applications for priority. (See *id.*) Because the Court has rejected JHU’s arguments, at summary judgment, that the ’240 application cannot rely on 454’s provisional applications for priority, the Court will deny JHU’s anticipation argument with respect to the ’240 application at this time.

yet capable of hybridizing.⁸ Thus, to comply with the enablement requirement, the '240 application must enable the full scope of the Count as further construed above.

The '240 application includes the following in its specification: "For use with the present invention, capture beads **with or without** attached nucleic acid template are suspended in a heat stable water-in-oil emulsion." ('240 application (D.I. 73-1 Ex. C) at 9:3-4) (emphasis added) Dr. Tyagi opines as follows in his expert report with respect to the above excerpt from the '240 application:

[W]hen 454 Life Sciences did add some words to its application regarding such a method of separate introduction of bead and template in 2004, its disclosure was no more than a minimal mention. It provided no teaching of how to deliver template separate from beads and did not provide any description that would ensure that such a method would work. 454 Life Sciences did not provide an enabling description that one of skill in the art could have followed to successfully practice the full scope of the Count.

(D.I. 74-2 Ex. 3 ¶ 43) Although it appears that 454 cites no expert opinion or other evidence in its opposition brief that responds to Dr. Tyagi's opinion on this particular issue, the Court will not grant summary judgment based solely on the somewhat conclusory testimony of Dr. Tyagi. Therefore, JHU has not met its burden⁹ at summary judgment to prove this issue by a preponderance of the evidence.¹⁰

⁸This construction is based on the same claim construction record relied on in the Court's Memorandum Opinion on Claim Construction (D.I. 56).

⁹JHU, as the junior party in the Interference, bears the initial burden of production on this issue, as this issue could be dispositive of priority. *See Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1379 (Fed. Cir. 2009).

¹⁰The complete absence of **any** record before the Board on this issue also weighs against granting summary judgment on this issue. The Court finds it necessary to conduct a trial on this

The Court will deny JHU's motion with respect to JHU's claim that the '240 application fails to adequately describe and enable the Count.

IV. 454'S PARTIAL MOTION FOR SUMMARY JUDGMENT (D.I. 70)

454 moves for partial summary judgment that 454's priority date with respect to the Count is April 23, 2003 – the filing date of the '071 application – based on a claim of priority to the '071 application. JHU argues that the '071 application fails to comply with the written description and enablement requirements, as discussed above. JHU supports its arguments with expert testimony from Dr. Tyagi. (*See* D.I. 76 at 3) (citing Expert Report of Dr. Tyagi (D.I. 74-2 Ex. 3) at 30-34, 38-44; Responsive Expert Report of Dr. Tyagi (D.I. 74-11 Ex. 8) at 34-45, 48-70) Dr. Tyagi's testimony creates a genuine issue of material fact with respect to 454's Motion. Thus, the Court will deny 454's Motion.¹¹

V. CONCLUSION

JHU's Motion (D.I. 68) will be **GRANTED IN PART** and **DENIED IN PART**, as discussed above. 454's Motion (D.I. 70) will be **DENIED**. An appropriate Order follows.

issue to further develop the record before deciding the issue.

¹¹In addition to what 454 formally moved for at summary judgment (i.e., that 454 is entitled to the filing date of the '071 application as its priority date), 454 made a number of requests for additional rulings in its opposition brief to JHU's motion. (*See* D.I. 81 at 19-20) (JHU listing 454's requests for additional rulings) The Court declines to address these requests, which are improperly asserted for the first time in an opposition brief. *See Holland v. Simon Prop. Grp., Inc.*, 495 F. App'x 270, 273 (3d Cir. 2012) ("The District Court correctly declined to consider claims . . . asserted for the first time in [a party's] summary judgment opposition brief.").